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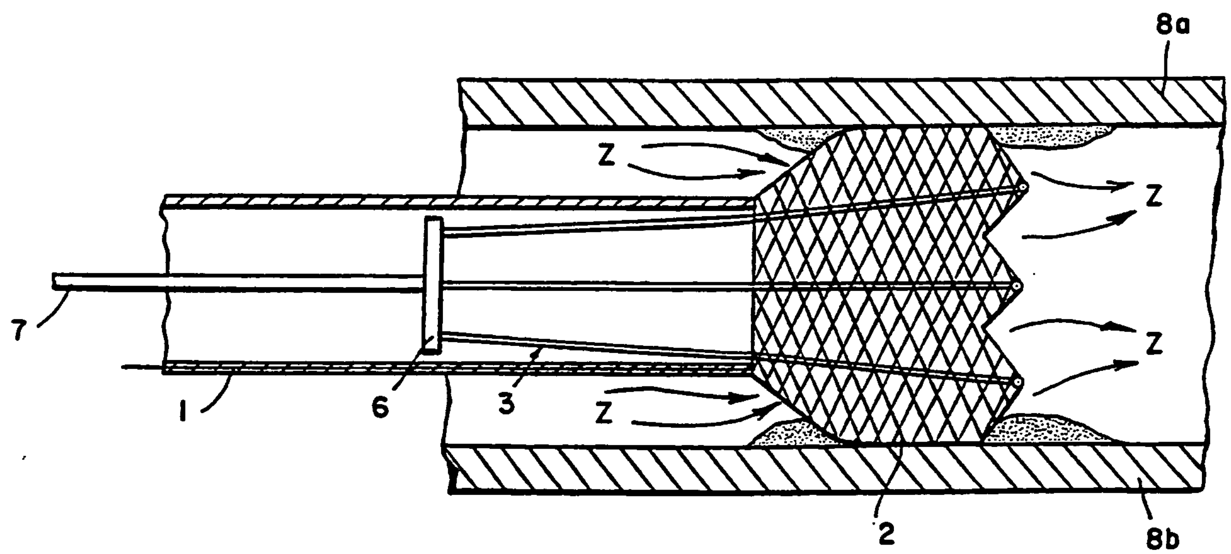

(57) Abstract

A catheter for use in angioplasty and other medical procedures is disclosed. The catheter features a flexible wire mesh tip (2) movably attached at a distal end of the catheter (1), the tip being expandable from a contracted position which it is first in when the catheter is deployed inside the lumen of a vessel, to stretch open the lumen and eliminate a flow obstruction therein, such as is caused by plaque deposits; the tip subsequently being returnable to its contracted position inside the catheter when the catheter is withdrawn from the lumen of the vessel. Radio frequency energy may additionally be used to weld the source of the flow obstruction to the wall of the lumen leaving a conduit of sufficiently expanded diameter to allow resumption of normal flow in the vessel.

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CATHETER WITH EXPANDABLE WIRE MESH TIP

Catheters having inflatable balloons mounted on their distal ends are a commonly used apparatus for entering blood vessels to expand and open strictures at remote sites in a non-invasive manner.

In conventional balloon catheters, vessel expansion is achieved by inflating the balloon on the catheter tip at the site of the obstruction. The balloon expands radially outward, thereby expanding the place in the blood vessel where it is located.

One disadvantage of the conventional balloon catheter is that blood flow through the lumen of the vessel in which the balloon is to be inflated, which is already severely reduced because of the stricture, is momentarily completely cut-off when the balloon is inflated and exerting pressure against the stricture-causing mass and/or wall of the vessel. If such a condition is maintained for an extended period of time it is possible that damage to or necrosis of the tissue material of the vessel wall may occur.

Accurate control of the extent of inflation of the balloon may also be difficult to achieve in some circumstances with conventional balloon catheters. If inflation is not carefully monitored and controlled, it is possible to overinflate the balloon which in turn may cause a stretching and weakening of the vessel wall.

In the particular application of balloon catheters to angioplasty, moreover, there is a possibility, which occurs at a frequency on the order of about 5% of the cases, of the abrupt reclosure of an expanded artery after balloon angioplasty. This is generally due to a dissection of the arterial wall obstructing the lumen, to elastic recoil of the arterial wall, or to spontaneous spasm of the arterial wall.

Accordingly, a catheter featuring a novel means of lumen expansion at its distal end has been developed. The present invention utilizes an expandable wire mesh tip attached to the distal end of the catheter. In certain embodiments of the catheters, the wire mesh tip is expanded at the situs of a stricture in a lumen through which the catheter is being manipulated by means of a control mechanism which pulls on the mesh to shorten the length of the mesh device while simultaneously expanding its diameter. In certain other embodiments, a wire mesh material with intrinsic shape restoring properties is employed as the material of the wire mesh tip, with the wire mesh tip being fabricated to have a default position in an expanded state, and a moveable sheath being utilized as the means to alternatively contain the wire mesh tip in a contracted position.

A catheter for insertion in the lumen of a vessel according to the present invention generally includes the elements of a tubular catheter body, a wire mesh tip and means for manipulating the wire mesh tip.

The tubular catheter body is of substantially tubular shape, open at both ends, has an inner diameter and an outer diameter, a fixed length, and a proximal end and a distal end.

The wire mesh tip is capable of being configured to have a substantially cylindrical shape of variable dimensions, open at both ends, with the wire mesh tip having a variable diameter, a variable length, and a proximal end and a distal end. The wire mesh tip is attached at its proximal end to the distal end of the catheter body, such that the wire mesh tip and the catheter body are coaxially joined in a lengthwise direction.

The means for manipulating the wire mesh tip is utilized to move the wire mesh tip back and forth between a contracted position, wherein the tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than the inner diameter of the tubular catheter body, and a contracted position length, and at least one expanded position, wherein the tip is configured to have dimensions of an expanded diameter greater than the contracted diameter and not greater than thirty times the outer diameter of the catheter body, and an expanded position length that is shorter than the contracted position length.

Fig. 1 is a side view of the distal end of one embodiment of a catheter according to the present invention, with a wire mesh tip shown in a contracted position.

Fig. 2 is a side view of the distal end of the catheter of Fig. 1, with the wire mesh tip shown in an expanded position.

Fig. 3 is an end view of one embodiment of a circular control wire connection plate inside a catheter according to the present invention.

Fig. 4 is a side view of a catheter according to the present invention, with a wire mesh tip in an expanded position inside a vessel, and showing the available flow path.

Figs. 5 a, b and c are front end views of alternative embodiments of elements of the wire mesh tip expansion-contraction control mechanism according to the present invention.

Figs. 6 a and b are side views of alternative embodiments of the wire mesh tip expansion-contraction control mechanism according to the present invention.

Fig. 7 is a side view of an alternative embodiment of a catheter according to the present invention, with a wire mesh tip, shown in a contracted position, and an expansion-contraction control mechanism.

Fig. 8 is a side view of an alternative embodiment of a catheter according to the present invention, with a wire mesh tip, shown in an expanded position, and an expansion-contraction control mechanism, and showing the available flow path.

Fig. 9 is a longitudinal view of the distal end of a catheter according to the present invention with a wire mesh tip further provided with two parallel helical bipolar electrode leads for supplying RF energy to the wire mesh tip.

Fig. 10 is an enlarged view of the distal end of the tubular catheter body and wire mesh tip of Fig. 9 showing details of the path of the two helical bipolar electrode leads through an annular space between the inner and outer walls of the catheter body and attachment of the leads to the wire mesh tip.

Fig. 11 is a side view of an alternative embodiment of a catheter according to the present invention, with a self-expandable wire mesh tip, shown in a constrained position.

Fig. 12 is a side view of the catheter of Fig. 11, with the wire mesh tip shown in an expanded position.

Fig. 13 is a side view of another alternative embodiment of a catheter according to the present invention, with a self-expandable wire mesh tip open at both ends for maximum blood flow.

Fig. 14 is a cross-section view of the catheter of Fig. 13.

Generally expansion of the wire mesh tip at the end of the catheter is accomplished by compressing the wire mesh tip in a direction along the common longitudinal axis of the tip and the catheter. In certain embodiments of the catheter according to the present invention, this is achieved by actuating an external remote control means which causes a pulling force to be exerted on longitudinal tip control means attached at one end to the leading edge of the wire mesh tip. The control means runs from the points of attachment to the distal end of the wire mesh tip, axially along the length of the wire mesh tip, and then through the tubular body of the catheter to external remote control means to which the opposite end of the tip control means is attached. The tip control means has several alternative embodiments, as will be described, including one embodiment with a plurality of branch control wires attached

at one end to the wire mesh and at the other end to one face of an intermediary control plate, with a single control element attached to an opposite face of the control plate and extending along and out from the catheter, and another embodiment which utilizes only a single control element attached to the wire mesh by a front plate. In the embodiment of the apparatus which utilizes a plurality of branch control wires, the tip control means for manipulating the wire mesh tip back and forth between its contracted position and its at least one expanded position generally includes the elements of a plate, a control element, a plurality of branch control wires, and remote control means.

The plate has a diameter substantially equal to and not greater than the inner diameter of the tubular catheter body. The plate has a front face facing in the direction of the distal end of the catheter body and a back face facing in the direction of the proximal end of the catheter body. In a preferred embodiment, the plate is circular or substantially circular in shape. Alternatively, the plate can be square, rectangular or polygonally shaped, preferably having at least six sides. The plate is oriented in a plane perpendicular to the longitudinal axis of the catheter body, such that a clearance is provided between the plate and the inner diameter of the tubular catheter body to enable movement of the plate back and forth along the longitudinal axis of the catheter body.

The plurality of branch control wires, each having a proximal end and a distal end, are each attached at their distal ends to the distal end of the wire mesh tip at selected points around the circular perimeter of the cylindrically shaped wire mesh tip at the distal end of the tip. The wire mesh tip is preferably open at both ends to enable the maximum possible flow through the wire mesh tip. The branch control wires have a length greater than the length of the wire mesh tip in its contracted position, such that the branch control wires extend longitudinally from their points of attachment at the distal end of the wire mesh tip parallel to the length of the wire mesh tip in a direction toward the proximal end of the catheter body, with each branch control wire being attached at its proximal end to the front face of the plate at selected points on the front face of the plate. When the wire mesh tip is in its contracted position, having its maximum length, the plate is positioned at a first position thereof, and the branch control wires are positioned at a first position thereof, having a maximum component of their length that is parallel to and coaxial with the longitudinal axis of the catheter body. When the wire mesh tip is in an expanded position, the plate is positioned at a

second position thereof, wherein the plate extends further toward the proximal end of the catheter body than when the plate is in its first position, and the branch control wires are positioned at a second position thereof, having a component of their length that is parallel to and coaxial with the longitudinal axis of the tubular catheter body, which is shorter than the maximum component when in the first position. Alternative embodiments of the apparatus according to the present invention can incorporate from 2 to 12 branch control wires. A preferred embodiment utilizes six branch control wires.

The control element having a proximal end and a distal end, is attached at its distal end to the back face of the plate, and extends longitudinally away from the plate through the tubular catheter body, coaxially with the longitudinal axis of the tubular catheter body, in a direction toward the proximal end of the tubular catheter body. The control element exits from the proximal end of the tubular catheter body and terminates at the proximal end of the control element. The control element is a wire or a solid rod of sufficient diameter and rigidity to transmit a pulling force while remaining flexible, and not kinking. Alternatively, a hollow tube can be used as the control element in place of a wire or solid rod. The maximum diameter of the control element is less than the inner diameter of the tubular catheter body, so that an annular space remains between the outer wall of the control element and the inner wall of the tubular catheter body.

The proximal end of the main control element exits at the proximal end of the tubular catheter body, and is attached to the remote control means for enabling remote actuation to cause the wire mesh tip to change its position from its contracted position, in which the wire mesh tip is maintained while the catheter is being deployed in the lumen of a vessel, to its the expanded position, in which the wire mesh tip is maintained while an obstruction in the lumen is compressed against the walls of the lumen to restore circulation through the lumen. The remote control means is also capable, alternatively, of reversible actuation to cause the wire mesh tip to change position from its the expanded position to its contracted position in order to enable withdrawal of the catheter from the lumen.

The wire mesh tip is caused to move from its contracted position to its expanded position by actuating the remote control means in such a way as to exert a pulling force on the proximal end of the control element causing the control element to move in a longitudinal direction parallel to the longitudinal axis of the tubular catheter body, towards the proximal end of the tubular catheter body. The pulling force on the

control element is transmitted to the plurality of branch control wires by the plate, causing the plate and the branch control wires to be displaced from their respective first positions to their respective second positions and causing the distal end of the wire mesh tip to be moved from its contracted position to its expanded position.

Conversely, deactuation of the remote control means to terminate the pulling force on the control element causes the control element, the plate and the branch control wires to return from their respective second positions to their respective first positions, by moving those elements in a direction towards the distal end of the tubular catheter body, thereby causing the wire mesh tip to return to its contracted position from its expanded position.

Referring to Fig. 1, depicting a preferred embodiment utilizing a plurality of branch control wires, distal end of catheter 1 with wire mesh tip 2 is shown in its contracted position of diameter D_1. A plurality of branch control wires 3, three being shown as 3a, b and c, are attached to the leading edge of the mesh 4 around its periphery at connections 5, the three connections shown as 5a, b and c corresponding to the points of connection of the three branch control wires, respectively. The branch control wires 3 are oriented longitudinally with the mesh device and coaxially with the principal longitudinal axis of the overall catheter. The branch control wires 3, have length L, which is longer than the length of the mesh tip 2 in its contracted position L_1. The wires extend an initial distance L_2 into the annulus of the catheter when the mesh tip is in its contracted position. A total of from 2 to about 12 branch wires 3 may be utilized around the periphery of the wire mesh tip. In one preferred embodiment, a total of 6 branch control wires are utilized, equidistantly spaced around the periphery. The ends of the branch control wires opposite to those attached to the leading edge of the wire mesh tip are attached to an outer, front face of circular plate 6, which has a diameter slightly smaller than the inside diameter of the tubular catheter body. Referring to Fig. 3, one preferred configuration of circular plate 6, accommodating a total of 6 branch control wires 3 a-f attached to the wire mesh tip, is shown in end view. The plate 6 has a diameter D which is slightly smaller than the inside diameter (ID) of tubular catheter body 1 to enable free movement of plate 6 axially along the catheter.

A control wire 7 is attached to the opposite, back face of circular plate 6 and extends therefrom along the length of catheter 1 to a remote control means external to the catheter (not shown) which enables an operator to pull on the control wire 7. This

pulling force is transmitted to the branch control wires 3 attached to the wire mesh tip 2 via the circular plate 6 to which all branch control wires are attached, thereby causing the wire mesh tip 2 to move from its contracted position to an expanded position. Alternatively, control wire 7 is a hollow tube.

Referring to Fig. 2, the distal end of catheter 1 with wire mesh tip 2 attached thereto is shown in its expanded position of diameter D_2. Control wire 7 has been pulled in the direction of arrow W axially through the annulus of the tubular catheter body away from the distal end of the catheter. This causes circular plate 6 to which control wire 7 and all branch control wires 3 are attached to move from position X shown in Fig. 1 to position Y shown in Fig. 2. In this expanded position, the portion of the total length L of branch control wires 3 in the annulus of the catheter changes from L_2, shown in Fig. 1 for the contracted position to L'_2 for the expanded position of Fig. 2. At the same time, the length of the wire mesh tip and hence the portion of the length of branch control wires 3 therein is shortened from L_1 shown in Fig. 1 for the contracted position, to L'_1 shown in Fig. 2 for the expanded position.

The expansion of wire mesh tip 2 on the distal end of catheter 1 from its contracted position shown in Fig. 1, in which condition it is emplaced in the lumen of a vessel, to its expanded position shown in Fig. 2, causes an increase in the effective passageway in the lumen of the vessel available for blood flow of width D_2-D_1, where D_2 is the diameter of an unconstricted vessel and D_1 is the diameter of a vessel with a stricture. Expansion of the wire mesh device at the stricture will cause a pliable stricture-causing material, such as plaque, to be compressed at the walls of the vessel and open the passageway by a width $\Delta D = D_2 - D_1$, for improved flow.

The wire mesh tip on the distal end of the catheter, once having been expanded according to the foregoing, is again fully retractable to its initial position, wherein the catheter and tip can be withdrawn from the vessel. Reconfiguration of the wire mesh tip to its contracted position is accomplished by a reversal of the procedure used to expand the tip. The operator deactuates the external remote control means which removes the pulling force exerted on the control wire means and associated elements.

The catheter with wire mesh tip at its distal end, according to the present invention, has several advantages over conventional balloon catheters.

The catheter with wire mesh tip allows precise control of the diameter to which the mesh is expanded, thereby eliminating the possibility of over-expansion and possible consequent damage to the vessel.

Another advantage of the catheter and wire mesh tip system of the present invention is that the system does not totally occlude the blood vessel when the wire mesh tip is expanded. Even in its fully expanded state, blood will continue to flow through the open ended, generally cylindrically-shaped wire mesh tip along a flow path from the outer wall of the catheter to the edge of the wire mesh tip.

Fig. 4 shows catheter 1 with wire mesh tip 2 in its expanded position in place in a vessel whose walls are shown in side view by 8a, b. The arrows designated z define the flow path through the blood or fluid permeable mesh even when the mesh device is in its expanded position.

The wire mesh tip of a catheter according to the present invention can be fabricated from any type of wire mesh material with a mesh size that has sufficient permeability to allow the flow of blood or whatever fluid is flowing through the vessel in which the catheter is being utilized through the mesh when the tip is in its expanded position, in order that the lumen in which the catheter is being manipulated does not become totally occluded to flow when the mesh tip is in the expanded position.

The wire mesh material itself can be fabricated from any biologically inert material. It is preferable that the wire be metal, although certain inert plastics having sufficient strength may also be used. Stainless steel, titanium, titanium alloy, nitinol (nickel-titanium alloy), and vitallium alloy are suitable metallic materials of construction of the wire mesh. High molecular weigh polyethylene is a suitable plastic material of construction.

The wire mesh material can be made in a variety of patterns. Braided, woven and knit designs can be utilized as long as the fineness of the mesh size is greater than the molecular size of the fluid to be transmitted therethrough, so that fluid flow is not prevented by the mesh.

The extent of compression of the flow obstructing material in the vessel that is effected by expansion of the wire mesh tip is determined in part by the fineness of the mesh material and the pattern that it forms which is utilized. Thus, if a tightly woven mesh is used, the flow obstructing material will be fairly evenly compressed against the wall of the vessel, whereas if a more loosely woven wire mesh is utilized, compression

of the flow obstructing material against the wall of the vessel will occur only where the mesh comes in contact with the material. There will be little or no compression in the interstices between the mesh. In this case, a waffle pattern will be impressed on the flow obstructing material. If the mesh material is sharp, it may cut into the flow obstructing mass causing particles of it to be cut away.

Rather than having particles of the flow obstructing material become cut loose or abrade from the vessel wall and be free to circulate through the vessel, it is instead, desirable to either weld the material in a compressed state to the vessel wall or ablate the material. This is accomplished by provision for alternative means for welding or ablating the material, such as through the application of radio frequency energy to the material, as is described in detail below.

The wire mesh tip expansion-contraction controlling mechanism of the apparatus of the present invention can also be fabricated in a variety of alternative ways to the control element-plate-branch control wires combination of the embodiment discussed above. According to such alternative embodiments of the catheter, which also generally include a catheter body, a wire mesh tip and means for manipulating the wire mesh tip, the means for manipulating said wire mesh tip back and forth between its contracted position and its at least one expanded position includes a plate-like element having a diameter or an equivalent diameter substantially equal to and not greater than the inner diameter of the tubular catheter body and having a front face facing in the direction of the distal end of the tubular catheter body and a back face facing in the direction of the proximal end of the tubular catheter body. The plate-like element is oriented in a plane perpendicular to the longitudinal axis of the tubular catheter body, and is attached to the wire mesh tip around the circular perimeter of the cylindrically shaped wire mesh tip at the distal end of the wire mesh tip. The plate-like element attached to the leading edge of the open cylindrical wire mesh tip around the periphery thereof is preferably circular in shape, but can also be square, rectangular or polygonally shaped, preferably having at least five sides. The plate-like element is generally a solid plate, however, according to other alternative embodiments, it is alternatively an element selected from the group consisting of an annulus and a perforated plate.

These embodiments also include a control element, which alternatively is a wire, a solid rod or a hollow tube, having a proximal end and a distal end, attached at its

distal end to the back face of the plate-like element and extending longitudinally away from the plate-like element through the tubular catheter body, coaxially with the longitudinal axis of the tubular catheter body, in a direction toward the proximal end of the tubular catheter body, and terminating at the proximal end of the control element, exiting from the proximal end of the tubular catheter body. The maximum diameter of the control element is less than the inner diameter of the tubular catheter body, leaving an annular space between the control element and the inner wall of the tubular catheter body. When the plate-like element is an annulus, preferably an annular ring, the mechanism for manipulating the wire mesh tip further includes a plurality of supporting struts for attaching the control element to the annular ring. One end of each of the plurality of supporting struts is attached to a solid outer portion of the annular ring around the periphery thereof, and the opposite end of each of the plurality of said supporting struts is attached to the control element. In one preferred arrangement, the plurality of supporting struts are oriented co-planar with the annular ring and the distal end of the control element, and in an alternative preferred arrangement, they have a portion of their length non-coplanar with the annular ring, which portion of their length extends axially with the control element in a direction towards the proximal end thereof. Alternative embodiments of the control mechanism of this embodiment of catheter according to the present invention can have from 2 to 12 supporting struts. A preferred embodiment has from 3 to 8 supporting struts.

When the plate-like element is an element selected from a solid plate and a perforated plate, the catheter further includes a plurality of supporting struts each attached at one end thereof to the plate-like element around its periphery, and at an opposite end of each of the plurality of supporting struts to the control element, such that the supporting struts have a portion of their length extending axially with the control element in a direction towards the proximal end thereof.

Finally, the wire mesh tip manipulating means for these alternative embodiments also includes remote control means to which the proximal end of the control element is attached, for enabling remote actuation to cause the wire mesh tip to move from its contracted position, alternatively to an intermediate partially expanded position or to the fully expanded position at which an obstruction in the lumen of the vessel in which the catheter is deployed is compressible against walls of said lumen in order to restore circulation through said lumen. The remote control means is also utilized to later cause

the wire mesh tip to return to its initial contracted position to enable withdrawal of said catheter from the lumen.

Figs. 5, 6, 7 and 8 show elements of the foregoing alternative wire mesh tip control mechanisms and their employment.

In one alternative embodiment of the control mechanism shown in Fig. 5 a, an annular ring (annulus) 9 is utilized. Annular ring 9 is attached to the leading edge of the periphery of wire mesh tip 2, shown in Fig. 6. A control wire 11 is utilized to move the ring in a longitudinal direction along the axis of the tip and catheter to cause the wire mesh tip to move from its contracted position to an expanded position and back. Control wire 11 is attached to annular ring 9 by a plurality of supporting struts 10 which are attached at one of their ends to the edge of the ring and at their opposite end to control wire 11. Fig. 5a shows one example of such an annular ring control mechanism having four struts 10a-d equidistantly distributed around the perimeter of the annular ring 11, by which the ring 11 is attached to main control wire 11. The supporting struts 10 can be positioned such that they are within the plane of the ring 9, or they may have a portion extending parallel to or at an angle with their point of attachment to control wire 11 and their point of attachment to annular ring 9, such that the points of attachment to the ring and the control wire are in different planes perpendicular to the axial direction of the catheter as shown in Fig. 6a. The space inside annular ring 9 is an additional path available for blood or fluid flow when the wire mesh tip is in an expanded position, as shown by arrows X in Fig. 8.

Other alternative embodiments of the control mechanism, utilizing a solid plate and a perforated plate, respectively, are shown in Figs. 5b and c. The solid, circular shaped plate element 12 of Fig. 5b is also attached to the leading edge of the wire mesh tip around its periphery, but allows for direct attachment of control wire 11 to the rear face of the plate. Circular plate 12 can be more securely attached to control wire 11 by the use of a plurality of reinforcing struts 10 distributed around the periphery of the plate with one end attached thereto and the other end attached to control wire 11, as shown in Fig. 6b. The solid circular control plate 12, however, does not present additional flow path area for fluid flow. Where such a control element is utilized, the flow path for fluid flow with the mesh tip in an expanded position is limited to flow channels through the wire mesh itself, as shown by arrows z in Fig. 8.

Another alternative embodiment of the control mechanism utilizes a perforated plate, preferably in the shape of a circular disk, as shown in Fig. 5c. The perforated disk 13 embodiment of the control element offers the advantage of a more solid point for attachment of control wire 11, as with the solid circular plate embodiment 12, while allowing for additional channels for fluid flow through the perforations, when the mesh tip is in the expanded position, shown by arrows X in Fig. 8, as with the annular ring element.

In certain alternative embodiments of the catheter according to the present invention, the wire mesh tip is fabricated from a wire mesh material having intrinsic shape-restoring properties, with the wire mesh tip being fabricated to have a default position in its expanded position. In such an embodiment, the tip is maintained in a contracted state by a sheath which in a first position surrounds the tip and exerts a restraining force which holds the wire mesh together. When it is desired to expand the tip, the sheath is retracted to a second position by moving it in a direction toward the proximal end of the catheter body such that it no longer surrounds the wire mesh tip, thereby causing the wire mesh tip to expand without the need for the use of further control means, due to the nature of the material of the wire mesh tip and its having been fabricated in such a manner that a default position of the wire mesh tip, when no external restraining forces are applied to it, is in its expanded position. The sheath in these embodiments essentially corresponds to the tubular catheter body of the previously described embodiments. The wire mesh tip is returnable to its contracted position when the sheath is moved in a direction toward the distal end of the catheter body, into the sheath's first position, wherein it again surrounds the wire mesh tip and exerts a restraining force thereupon, causing the wire mesh tip to remain in its contracted position while the restraining force is exerted by the sheath The proximal end of the wire mesh tip is attached to a control element, which depending upon the application of use of the catheter, is alternatively a rod, a tube or an open coil.

Referring to Figs. 11 and 12, which illustrate this alternative embodiment, the wire mesh of wire mesh tip 2 is bonded to open coil 23 along a segment of the length of the coil at a point 25. A recovery tube or sheath 15 is used to guide the catheter into position over a guidewire 17. In Fig. 11, the wire mesh tip 2 is shown in the contracted position with the sheath in place; while in Fig. 12, the wire mesh tip 2 is shown in the expanded position, the sheath 15 having been retracted to allow the shape-restoring

wire mesh material to expand and deploy the wire mesh tip 2; the flow path for fluid flow with the mesh tip in the expanded position is limited to flow channels through the wire mesh itself, as shown by arrows z' in Fig. 12. The wire mesh tip is fabricated in such a way that its expanded position is the default position when unconstrained, due to the shape-restoring properties of the material, which causes the tip to assume that configuration when the restraining sheath is retracted.

In another alternative embodiment of a wire mesh tipped catheter according to the present invention, which also utilizes a material for the wire mesh which has intrinsic shape-restoring properties, and the wire mesh tip is fabricated to have a default position in its expanded position, the catheter also includes a control element, which is alternatively a rod, a tube or an open coil as in the above embodiment, which cooperates with the wire mesh tip, and can be alternatively either attached or unattached thereto, and also includes as the means for manipulating the wire mesh tip, a string passed through the open coil, with a portion of the string being woven through the wire mesh tip, such that in order to cause the wire mesh tip to assume its contracted position, the string is pulled in a direction toward the proximal end of the catheter and inside the open coil, thereby causing that portion of the string woven through the wire mesh tip to shorten, and in turn, causing the wire mesh tip to partially contract. This alternative embodiment of the catheter also utilizes the movable outer sheath, as described above, which corresponds essentially to the tubular catheter body of previously described embodiments incorporating the control element-plate mechanism for manipulating the wire mesh tip. The sheath is capable of surrounding the wire mesh tip, and has a first position, in which the movable outer sheath surrounds the wire mesh tip, and a second position, in which the movable outer sheath does not surround the wire mesh tip, such that upon manipulation of the movable outer sheath in a direction toward the distal end of the catheter, from the second position to the first position of the outer sheath, a remaining uncontracted portion of wire mesh tip is caused to contract further such that the wire mesh tip is movable to its expanded position, first by manipulation of the outer sheath in a direction toward the proximal end of the catheter, from the first position to the second position of the outer sheath, to partially expand the wire mesh tip, by releasing the distal end of the wire mesh tip, and subsequently releasing the string, allowing the intrinsic shape-restoring force of the wire mesh tip to fully expand the proximal end of the wire mesh tip.

Referring to Figs. 13 and 14, which illustrate this embodiment, the wire mesh of wire mesh tip 2 is bonded to an open coil 23 at a single connection point 25. A "purse string" 18 is inside of the coil and is woven through the wire mesh tip. The diameter of the wire mesh tip is reduced prior to reinserting the tip in the sheath 15 by retracting or pulling back on the purse string in order to contract the wire mesh tip for recovery and removal from the vessel in which it has been deployed. The flow path for fluid flow with the mesh tip in the expanded position is limited to flow channels as shown by X′ in Fig. 13. This embodiment is shown in cross section in Fig. 14.

The wire mesh tip of all embodiments of catheter according to the present invention which utilize a control element-plate type mechanism for manipulating the wire mesh tip are capable of being configured in a number of positions, from fully contracted, through intermediate positions of partial expansion, to a fully expanded position. In each of the plurality of intermediate positions of partial expansion between the fully contracted position and the fully expanded position, the diameter of the wire mesh tip is greater than its diameter in the fully contracted position, less than the maximum diameter in its fully expanded position, and not greater than its maximum diameter of thirty times the outer diameter of the tubular catheter body. The length of the wire mesh tip extending parallel to the axial direction of said catheter body in an intermediate position is shorter than its length in the contracted position, and greater than its length in its fully expanded position.

For all such embodiments, the wire mesh tip is alternatively configurable from its fully contracted position through selected intermediate positions to its fully expanded position; from its fully expanded position through selected intermediate positions to its fully contracted position; from a first selected intermediate position to another selected intermediate position which is alternatively more expanded or more contracted than the first intermediate position, or from an intermediate position to the fully contracted or fully expanded position.

The position and state of configuration of the wire mesh tip with respect to its expansion or contraction is proportional to the pulling force being exerted on the main control wire through the remote control means.

In the embodiments which utilize a wire mesh tip fabricated from an intrinsic shape-restoring material, and utilizing a movable sheath to deploy the wire mesh tip,

the wire mesh tip is only a bipositional device, capable of assuming alternatively only a fully contracted or a fully expanded position.

For all the embodiments of the wire mesh tip according to the present invention, the wire mesh tip is alternatively fabricated from a single piece of wire mesh which can be joined lengthwise side edge to side edge forming a seam in order to form an open cylindrical tip, or the wire mesh tip can be formed from a plurality of rectangular wire mesh panels, with each panel having a proximal end, a distal end and two sides, the sides being longer than the ends, further with each panel terminating in a forward section having an outwardly facing curvilinear edge, and each panel being longitudinally attached to an adjoining panel on both sides, to form a substantially cylindrical tip. In the embodiments of the apparatus which utilize a main control element-plate-branch control wires system as the means for manipulating the wire mesh tip, alternatively, all or selected ones of the panels have one of the plurality of branch control wires attached thereto, at their forward section.

According to the present invention, the wire mesh material of the wire mesh tip is fabricated in a braided, woven or knot pattern. The wire mesh material of the wire mesh tip has a mesh size that is permeable to the flow of fluid present in the lumen of the vessel in which the catheter is deployed. The wire mesh of the wire mesh tip is fabricated from a metal or plastic that is inert to fluid present in the lumen of the vessel in which the catheter is deployed. Such materials include stainless steel, nitinol, titanium, vitallium and polyethylene.

Depending on the pliability and compressibility of the flow obstructing mass, a vessel in which the effective passageway available for blood flow has been increased by the above procedure may maintain its widened diameter or it may gradually or even acutely return to a stenosed state. In the former case, this occurs by the redeposition of flow obstructing material such as plaque on the walls of the vessel at the same location using the compressed material as a nucleation site for new deposition, or in the latter case by the sudden re-expansion of the compressed mass of material to at or near its original vessel occluding diameter. Occurrence of the latter is particularly undesirable, as it may precipitate acute cardiovascular, particularly coronary, insufficiency resulting in a serious, possibly life-threatening, cardiovascular incident, manifested as a heart attack or stroke.

In order to prevent the re-occurrence of either type of occlusive condition, it is desirable that the flow obstructing material be removed rather than merely compressed.

It is known that radio frequency (RF) energy is effective in cutting or ablating plaque deposits on blood vessel walls, and for coagulating tissue.

Accordingly, certain embodiments of a wire mesh tipped catheter according to the present invention further include a wire for transmitting radio frequency energy. The wire extends the length of the tubular catheter body from the proximal end thereof to the distal end thereof. The wire is positioned in the annulus formed between the outer diameter of the inner tubular wall and the inner diameter of the outer tubular wall of the tubular catheter body, the wire being connected at a distal end thereof to the wire mesh tip.

A source for generating radio frequency energy connected to the wire at a proximal end thereof, external to the proximal end of the tubular catheter body is also provided.

In one embodiment, the wire for transmitting radio frequency energy is a main transmitting wire which is connected to the wire mesh tip at a plurality of points of attachment on the outer surface of the wire mesh through a corresponding number of branch transmitting wires extending from the main transmitting wire to the points of attachment.

For embodiments of catheters according to the present invention which utilize a plurality of branch control wires and a plate as part of the means for manipulating the wire mesh tip, radio frequency energy is delivered in one embodiment by means of an ablation electrode attached to the plate and insulated from the wire mesh tip. In these embodiments, a hollow tube is preferably utilized as the main control element to provide an annular space between the outer wall of the tubular control element and the inner wall of the tubular catheter body in which the wire for transmitting electrical energy is placed to insulate it from the inner lumen of the tubular control wire. The inner lumen of the tubular control wire also provides a convenient lumen through which suctioning of debris and fluids can be performed. This embodiment also includes a wire for transmitting electrical energy to the electrode. The wire extends through the length of the wire mesh tip, and is insulated therefrom. It further extends through the length of the tubular catheter body from the proximal end thereof to the distal end thereof, and is insulated from the wire for transmitting radio frequency energy to the wire mesh tip,

which is also contained in the annular space between the outer wall of the tubular control element and the inner wall of the tubular catheter body. Also included is a source for generating electrical energy for the ablation electrode, which is connected to the wire for transmitting electrical energy at the proximal end of the wire, external to the proximal end of the wire which is external to the proximal end of the tubular catheter body.

Referring to Fig. 9, a conducting wire 8 for supplying RF energy to all or a portion of the mesh tip is shown. The wire 8 is positioned in the annular space formed between the inner wall of the tubular catheter body and the outer wall of a tubular control wire, running axially along the length of the catheter from its proximal end, at which it is connected to a source of RF energy, to the distal end of the catheter, which interfaces with the proximal end of the wire mesh tip, and where the conducting wire is connected to the wire mesh tip at one location, or through a plurality of branching conducting wires (not shown), to a plurality of locations on the outer surface of the open cylindrical wire mesh tip.

The RF energy transmitting wire electrodes attached to the wire mesh tip can be either monopolar or bipolar.

Bipolar electrodes can be utilized with a braided wire mesh by running two leads to two parallel helical elements in the mesh and insulating all other members from those two members, by fabricating all other members of the braided mesh from electrically non-conducting material such as plastic or by providing insulation over the otherwise electrically conductive wires to make them non-conducting. The two parallel helical members should both be either right hand or left hand helixes so that their elements do not cross.

Fig. 9 shows how two parallel helical RF energy transmitting electrode leads 8a, b do not cross when attached to braided wire mesh tip 2.

Fig. 10 shows an expanded view of the distal end of catheter 1 showing the double wall tubular construction formed by the inner wall of the tubular catheter body, and the outer wall of a tubular control wire, and wire mesh tip 2 attached, with two RF transmitting leads 8a, b of a bipolar electrode running through the annular space between the inner and outer walls of the tubular catheter body and attached to the wire mesh tip as parallel helixes not in contact with one another.

An advantage of the embodiment of the catheter with wire mesh tip, further provided with an RF energy transmitting electrode attached to the mesh tip, is that it allows the RF energy to be transmitted through all or part of the mesh to cut, ablate or coagulate tissue.

For angioplasty applications, this allows for the capability of first expanding the mesh tip to compress the restrictive plaque or other mass and then coagulate to seal it in its compressed position to prevent its reexpansion and the restenosis of the vessel.

In the treatment of benign hypertrophy of the prostate, the system of the present invention with RF energy transmission capability can be utilized in a cutting mode to first expand the mesh tip and then rotate it while applying RF energy to the expanded mesh to cut out a plug of tissue to remove the urethral stricture.

The apparatus of the present invention, particularly the embodiment incorporating means for applying RF energy to the surrounding tissue can also be utilized in the treatment of percutaneous diskectomy, wherein the expanded wire mesh tip is first used to entrap tissue which is then ablated or cut with the RF energy.

Catheters utilizing alternative wire mesh tip actuation control means incorporating a plate-like element such as an annular ring 9, solid disk 12 or perforated disk 13, can be provided with bipolar or sesquipolar electrodes by using one or more wires of the mesh tip 2 as one electrode and the ring 9 or disk 12, 13 as the other electrode. The ring 9 or disk 12, 13 must be insulated from the wire mesh 2. Separate RF energy supplying leads are connected to the wire mesh 2 and to the ring 9 or disk 12, 13.

In such a configuration, the electrode connected to the front ring 9 or disk 12, 13 can function as an ablation electrode, while the electrode connected to the wire mesh tip is utilized for coagulation or welding plaque to the wall of the vessel.

For all of the embodiments of the catheter of the present invention, it has been found that the possibility of the occurrence of a thrombosis can be reduced by coating all or part of the catheter and the elements thereof which come in contact with blood in a lumen of a vessel with a non-thrombogenic material, such as heparin or hirudin.

For all applications, the elements of the catheter, and particularly the wire mesh tip can also be coated with an elastomeric material to facilitate movement of the catheter through the lumen by decreasing any tendency to adhere to the lumen wall. The preferred elastomeric materials include silicone and thermoplastic elastomers, such

as extruded and injection-molded elastomers, and particularly polyurethane and polyethylene.

It has also been found useful in the method of use of the catheter to prime it with one or more of a radiopaque solution to assist in placement of the catheter by monitoring it with an instrument capable of detecting a change in electromagnetic wave penetration; and a saline solution to give the outer surface of said catheter a blood pH compatible coating.

The method of use of catheters according to the present invention in procedures to remove a mass obstructing the lumen of a vessel to increase flow through the lumen, such as in angioplasty for the removal of plaque, in the treatment of benign hypertrophy of the prostate to remove prostatic tissue causing a urethral stricture, and in the treatment of percutaneous diskectomy to remove tissue, generally includes the steps of inserting the catheter with the wire mesh tip in a contracted position into the lumen of the vessel; advancing the catheter to the situs of the obstruction; expanding the wire mesh tip of the catheter to compress the obstruction and open the lumen for increased flow therethrough; maintaining the wire mesh tip in the expanded position for a sufficient time to maintain the obstruction in a compressed state so that it will remain compressed after the catheter is withdrawn; optionally utilizing electromagnetic energy such as radio frequency energy to ablate the obstruction; re-contracting the wire mesh tip; and withdrawing the catheter from the lumen.

The specific method utilized with catheters according to the present invention, the embodiments of which are as illustrated in Figs. 1-10, is described by the following procedure.

The catheter, having a flexible tubular body and a flexible open cylindrical wire mesh tip attached at a proximal end thereof to a distal end of the tubular catheter body, with the wire mesh tip being in an initial contracted position wherein the wire mesh tip is configured to have dimensions of a contracted diameter approximately equal to the inner diameter of the tubular catheter body and a contracted position length is first inserted into the lumen of the vessel to be cleared of an obstruction.

The catheter is then advanced through the lumen so that the wire mesh tip is positioned at the situs of the flow obstruction.

Remote control means external to the catheter and connected to the wire mesh tip by a control wire and associated means are then actuated to cause the wire mesh

tip to be reconfigured to an expanded position at the situs of the flow obstruction, such that the wire mesh tip has an expanded diameter greater than its contracted diameter and not greater than thirty times the outer diameter of the outer wall of the tubular catheter body and a length equal to an expanded length in the axial direction of the tubular catheter body that is shorter than the contracted length. The expansion of the diameter of the wire mesh tip at the situs of the flow obstruction produces a compression of flow obstructing material against the tubular wall of the lumen to widen the passageway for flow through the lumen.

Optionally, radio frequency energy supplied from a source external to the catheter and transmitted through at least one transmitting wire to the wire mesh tip to which a distal end of said at least one transmitting wire is attached, is utilized to energize the wire mesh tip to cut or ablate the flow obstructing material with which the wire mesh tip is in contact while in its expanded position.

Suction through the catheter is also optionally utilized to remove any debris formed during cutting or ablation.

The remote control means is then deactuated to cause the wire mesh tip to be restored to its the first contracted position.

Finally, the catheter is withdrawn from the lumen.

The specific method utilized with catheters according to the present invention, the embodiment of which is illustrated in Figs. 11-12, is described by the following procedure.

The catheter is first inserted into the lumen of the vessel to be cleared of an obstruction. The wire mesh tip is fabricated from a wire mesh material having intrinsic shape-restoring properties, with the wire mesh tip being fabricated to have a default position in an expanded position thereof, such that the wire mesh tip is initially in a contracted position wherein the tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than the inner diameter of the tubular catheter body and a contracted position length. The wire mesh tip is bonded to an open coil which acts as a control means. In the embodiment, moreover, the tubular catheter body is slidable with respect to the wire mesh tip and acts as means for manipulating the wire mesh tip, by functioning as a movable outer sheath for the wire mesh tip. The sheath (tubular catheter body), which in a first position surrounds the wire mesh tip in its contracted position, exerts a restraining force on the wire mesh tip

against expansion thereof to its default position, such that when the sheath is moved in a direction toward the proximal end of the catheter body from its the first position to a second position, wherein it no longer surrounds the wire mesh tip, the wire mesh tip is caused to expand to its said expanded position, due to the removal of said restraining force of the sheath on the wire mesh tip and the shape-restoring properties of the material of the wire mesh tip, which cause the wire mesh tip to expand in the absence of the restraining force from the sheath.

The catheter is then advanced through the lumen so that the wire mesh tip is at the situs of the flow obstruction.

The movable outer sheath (tubular catheter body) is then moved to its second position to cause the wire mesh tip to expand at the situs of the flow obstruction, such that the wire mesh tip has an expanded diameter greater than its contracted diameter and less than thirty times the outer diameter of the tubular catheter body and an expanded position length in the axial direction of the tubular catheter body that is shorter than the contracted position length. Expansion of the diameter of the wire mesh tip at the situs of the flow obstruction produces a compression of the flow obstructing material against the tubular wall of the lumen to widen the passageway for flow through the lumen.

Optionally, radio frequency energy supplied from a source external to the catheter and transmitted through at least one transmitting wire to the wire mesh tip to which the distal end of the at least one transmitting wire is attached, is utilized to energize the wire mesh tip to cut or ablate the flow obstructing material with which the wire mesh tip in its expanded position is in contact.

Suction through the catheter is also optionally utilized to remove any debris formed during cutting or ablation.

The wire mesh tip is returnable to its contracted position when the sheath is moved in a direction toward the distal end of the catheter body to its first position, wherein it again surrounds the wire mesh tip and exerts a restraining force thereupon, causing the wire mesh tip to remain contracted while the restraining force is exerted thereon by the sheath.

The movable outer sheath (tubular catheter body) is then moved to its first position to cause the wire mesh tip to be restored to its first, contracted position.

Finally, the catheter is withdrawn from the lumen.

The specific method utilized with catheters according to the present invention, the embodiment of which is illustrated in Figs. 13-14, is described by the following procedure.

The catheter is first inserted into the lumen of the vessel to be cleared of an obstruction. The wire mesh tip is fabricated from a wire mesh material having intrinsic shape-restoring properties, with the wire mesh tip being fabricated to have a default position in a second, expanded position thereof. The wire mesh tip cooperates with an open coil, such that the wire mesh tip is initially in a first contracted position wherein the wire mesh tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than the outer diameter of the outer tubular wall of the tubular catheter body, and a contracted position length. In this embodiment, moreover, the tubular catheter body acts as means for manipulating the wire mesh tip between its first and second positions, by functioning as a sheath for the wire mesh tip. The sheath has a first position in which it surrounds the wire mesh tip, and a second position in which it does not surround the wire mesh tip. The wire mesh tip manipulating means further includes a string which passes through the open coil, with a portion of the string being woven through the wire mesh tip, such that in order to cause the wire mesh tip to move from its first position to its second position, the outer sheath is first moved from its first position to its second position, to release the distal end of the wire mesh tip. The string is subsequently released to allow the intrinsic shape-restoring properties of the wire mesh tip to cause the proximal end of the wire mesh tip to fully expand. To cause the wire mesh tip to move from its second position to its first position, the string is first pulled in a direction toward the proximal end of the catheter, to thereby shorten the portion of the string woven through the wire mesh tip, partially contracting the wire mesh tip, and subsequently moving the outer sheath in a direction toward the distal end of the catheter, to move the outer sheath into its first position wherein it surrounds the wire mesh tip, thereby fully contracting the wire mesh tip.

The catheter is then advanced through the lumen so that the wire mesh tip is at the situs of the flow obstruction.

The movable outer sheath (tubular catheter body) is then moved proximally to its second position and the string is released to cause the wire mesh tip to expand at the situs of the flow obstruction, such that the wire mesh tip has an expanded diameter

greater than its contracted diameter and less than thirty times the outer diameter of the outer tubular wall of said catheter, and an expanded position length extending parallel to the axial direction of the catheter that is shorter than the first position length. Expansion of the diameter of the wire mesh tip at the situs of the flow obstruction produces a compression of flow obstructing material against the tubular wall of the lumen to widen the passageway for flow through the lumen.

Optionally, radio frequency energy supplied from a source external to the catheter and transmitted through at least one transmitting wire to the wire mesh tip to which the distal end of the at least one transmitting wire is attached, is then utilized to energize the wire mesh tip to cut or ablate the flow obstructing material with which the wire mesh tip in its expanded position is in contact.

Suction through the catheter is also optionally utilized to remove any debris formed during cutting or ablation.

The movable outer sheath (tubular catheter body) is then moved to its first position to cause the wire mesh tip to be restored to its first, contracted position.

Finally, the catheter is withdrawn from the lumen.

According to the method of use of the apparatus of the present invention, an embodiment of a catheter of the present invention is left in place in the lumen of a vessel to compress an obstruction therein and enlarge the flow path through the lumen for at least a sufficient time to cause the obstructed material to remain compressed against the lumen wall. The catheter may be left in place with the wire mesh tip in an expanded position for a period of up to about 48 hours, although that length of time is generally not required to cause a lasting compression of the obstructive material.

In those embodiments of the catheter which include means for delivery of radio frequency energy to the obstruction in order to cut or ablate the mass of obstructive material, radio frequency energy is applied only for a sufficiently long period of time to cut or ablate the material, which is generally not longer than several minutes, although the catheter may be left in position with the wire mesh tip in its expanded position for a longer period of time of up to about 48 hours, in order to continue to compress any remaining obstructive material against the wall of the lumen to increase the flow path through the lumen.

All embodiments of the catheter according to the present invention can also be utilized with and include as an element thereof, a guidewire to facilitate placement of

the catheter into the lumen of the vessel and advancement of the catheter to the situs of the obstruction. A guidewire lumen must be provided through the catheter from its proximal to its distal end to accommodate the guidewire. In those embodiments which utilize a control wire-plate mechanism to manipulate the wire mesh tip, the control wire can be a hollow tube and the plate has a hole through it to accommodate the guidewire.

When a guidewire is utilized, the above-described method of use of each embodiment of catheter equipped with a guidewire is preceded by an initial step, performed before insertion of the catheter into the lumen of the vessel, of inserting the guidewire into the lumen and advancing it through the lumen to the situs of the obstruction with at least a portion of the guidewire remaining external to the lumen at the point of insertion. The catheter is then placed on the guidewire and advancement of the catheter in the lumen to the situs of the obstruction according to the above-described methods of use proceeds along the guidewire.

All embodiments of the catheter according to the present invention can also include means for suctioning debris and fluids from the situs of removal of the obstructive mass through the catheter.

All embodiments of the catheter according to the present invention which utilize wire mesh tip control means, such as a control element-plate, and wherein the wire mesh tip extends beyond the distal end of the tubular catheter body when the tip is in a contracted position, with the wire mesh tip being unsheathed, can also be fitted with a slidable sheath to cover the wire mesh tip during insertion of the catheter to prevent the wire mesh tip from damaging the lumen of the vessel. Such a sheath is then retracted when the catheter is in place with the wire mesh tip at the situs at the obstruction before the wire mesh tip is expanded, and replaced when the catheter is to be withdrawn.

When the catheter is to be primed with one or more of a radiopaque contrasting solution to facilitate tracing its location; a saline solution to make it pH compatible with body fluids or blood in the vessel into which the catheter is to be inserted; or is to be created with a non-thrombogenic material to prevent blood clotting, such priming and/or coating steps are performed first, prior to insertion of the catheter into the vessel.

The foregoing embodiments of the wire mesh tipped catheter, its constituent elements and its method areas of use, according to the present invention, are not intended to be limiting. Further examples within the scope of the claims will be apparent to those skilled in the art.

CLAIMS

1. A catheter for insertion in the lumen of a vessel comprising in combination:

a tubular catheter body open at both ends, with an inner diameter and an outer diameter, a fixed length, and a proximal end and a distal end;

a wire mesh tip capable of being configured to have a substantially cylindrical shape of variable dimensions, open at both ends, said wire mesh tip having a variable diameter, a variable length, and a proximal end and a distal end, with said wire mesh tip being attached at its said proximal end to said distal end of said tubular catheter body, such that said wire mesh tip and said tubular catheter body are coaxially joined in a lengthwise direction; and

manipulation means for manipulating said wire mesh tip back and forth between a contracted position, wherein said tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than said inner diameter of said tubular catheter body, and a contracted position length, and at least one expanded position, wherein said tip is configured to have dimensions of an expanded diameter greater than said contracted diameter and not greater than thirty times said outer diameter of said tubular catheter body, and an expanded position length that is shorter than said contracted position length, said means for manipulating said wire mesh tip back and forth between its said contracted position and its said at least one expanded position comprising a means selected from the group consisting of first and second manipulation means, wherein

said first manipulation means comprises:

a plate having a diameter substantially equal to and not greater than said inner diameter of said tubular catheter body and having a front face facing in the direction of said distal end of said tubular catheter body and a back face facing in the direction of said proximal end of said tubular catheter body, said plate being oriented in a plane perpendicular to the longitudinal axis of said tubular catheter body, and such that a clearance is provided between said plate and said inner diameter of said tubular catheter body to enable movement of said plate back and forth along said longitudinal axis of said tubular catheter body;

a plurality of branch control wires, each having a proximal end and a distal end, with each branch control wire being attached at its distal end to said distal end of said

wire mesh tip at selected points around the circular perimeter of said cylindrically shaped wire mesh tip at its distal end, the branch control wires having a length greater than the length of said wire mesh tip in its said contracted position, such that said branch control wires extend longitudinally from their points of attachment at said distal end of said wire mesh tip parallel to the length of said wire mesh tip in a direction toward said proximal end of said tubular catheter body, with each branch control wire being attached at its proximal end to said front face of said plate at selected points on the front face of said plate and when said wire mesh tip is in its said contracted position, having its maximum length, said plate is positioned at a first position thereof, and said branch control wires are positioned at a first position thereof, having a maximum component of their length that is parallel to and coaxial with said longitudinal axis of said tubular catheter body, and further such when said wire mesh tip is in an expanded position, said plate is positioned at a second position thereof, wherein said plate extends further toward said proximal end of said tubular catheter body than when said plate is in its said first position, and said branch control wires are positioned at a second position thereof, having a component of their length that is parallel to and coaxial with said longitudinal axis of said tubular catheter body, which is shorter than said maximum component when in said first position;

a control element selected from the group consisting of a wire, a solid rod, and a hollow tube, said control element having a proximal end and a distal end, said control element being attached at its said distal end to said back face of said plate, and extending longitudinally away from said plate through said tubular catheter body, coaxially with said longitudinal axis of said tubular catheter body, in a direction toward said proximal end of said tubular catheter body, said control element exiting from said proximal end of said tubular catheter body and terminating at said proximal end of said control element; and

remote control means to which said proximal end of said control element exiting at said proximal end of said tubular catheter body is attached, for enabling remote actuation to cause said wire mesh tip to change its position from its said contracted position in which said wire mesh tip is maintained while said catheter is being deployed in the lumen of a vessel, to its said expanded position in which said wire mesh tip is maintained while an obstruction in the lumen is compressed against the walls of the lumen to restore circulation through the lumen, said remote control means also being

capable, alternatively, of reversible actuation to cause said wire mesh tip to change position from its said expanded position to its said contracted position in order to enable withdrawal of said catheter from the lumen;

wherein said wire mesh tip is caused to move from its said contracted position to its said expanded position by actuating said remote control means in such a way as to exert a pulling force on said proximal end of said control element causing said control element to move in a longitudinal direction parallel to the longitudinal axis of said tubular catheter body, towards said proximal end of said tubular catheter body, said pulling force being transmitted to said plurality of branch control wires by said plate, causing said plate and said branch control wires to be displaced from their respective said first positions to their respective said second positions and causing said distal end of said wire mesh tip to be moved from its said contracted position to its said expanded position; and

wherein deactuation of said remote control means to terminate said pulling force on said control element causes the elements including said control element, said plate and said branch control wires to return from their respective said second positions to their respective said first positions, by moving said elements in a direction towards said distal end of said tubular catheter body, thereby causing said wire mesh tip to return to its said contracted position from its said expanded position; and

said second manipulation means comprises:

a plate-like element having an equivalent diameter substantially equal to and not greater than said inner diameter of said tubular catheter body and having a front face facing in the direction of said distal end of said tubular catheter body and a back face facing in the direction of said proximal end of said tubular catheter body, said plate-like element having a shape selected from the group consisting of circular, square, rectangular and polygonal having at least five sides, and being oriented in a plane perpendicular to the longitudinal axis of said tubular catheter body, such that a clearance is provided between said plate-like element and said inner diameter of said tubular catheter body to enable movement of said plate-like element back and forth along said longitudinal axis of said tubular catheter body; with said plate-like element being attached to said wire mesh tip around the circular perimeter of said cylindrically shaped wire mesh tip at its said distal end;

a control element selected from the group consisting of a wire, a solid rod,and a hollow tube, said control element having a proximal end and a distal end, said control element being attached at its said distal end to said back face of said plate-like element and extending longitudinally away from said plate-like element through said catheter body, coaxially with said longitudinal axis of said tubular catheter body, in a direction toward said proximal end of said tubular catheter body, and terminating at said proximal end of said control element, exiting from said proximal end of said tubular catheter body; and

remote control means to which said proximal end of said control element is attached, for enabling remote actuation to cause said wire mesh tip to move from its said initial, fully contracted position, alternatively to an intermediate partially expanded position or to said fully expanded position at which an obstruction in the lumen of the vessel in which said catheter is deployed is compressible against the wall of said lumen in order to restore circulation through said lumen, and to then again cause said wire mesh tip to return to its said initial contracted position to enable withdrawal of said catheter from the lumen;

wherein said plate-like element attached to said wire mesh tip around the periphery of its said distal end is an element selected from the group consisting of a solid plate, a perforated plate, and an annulus;

wherein when said plate-like element is an annulus, said second manipulation means is further comprised by a plurality of supporting struts for attaching said control element to said annulus; such that one end of each of said plurality of supporting struts is attached to a solid outer portion of said annulus around the periphery thereof and an opposite end of each of said plurality of said supporting struts is attached to said control element; and wherein when said circular element is an element selected from the group consisting of a solid plate and a perforated plate, said second manipulation means is further comprised by a plurality of supporting struts each attached at one end thereof to said plate-like element around its periphery, and at an opposite end of each of said plurality of said supporting struts to said control element such that said supporting struts have a portion of their length extending axially with said control element in a direction towards the proximal end thereof;

wherein said wire mesh tip is caused to move from its said initial contracted position to a said intermediate partially expanded position or to its said fully expanded

position by actuating said remote control means to exert a pulling force on said control element causing said control element to move longitudinally parallel to the axis of said tubular catheter body in a direction towards the proximal end of said tubular catheter body, said pulling force being transmitted to said wire mesh tip through said plate-like element to which both said control element and said wire mesh tip are attached, causing said distal end of said wire mesh tip to be displaced from its said initial contracted position, in a direction closer towards said distal end of said tubular catheter body, resulting in a repositioning and a reconfiguration of said wire mesh tip from its initial contracted position, having an initial diameter substantially equal to yet less than said inside diameter of said tubular catheter body and a length equal to said contracted length, to a second fully expanded position having a larger diameter, greater than said initial diameter and not greater than thirty times said outside diameter of said outer wall of said tubular catheter body and a length equal to an expanded length, in the axial direction of said tubular catheter body that is shorter than said contracted length; and

wherein said wire mesh tip is then caused to return to its said contracted position from its said expanded position by deactuating said remote control means to terminate said pulling force on said control element, thereby causing said control element, and said plate-like element to return from their said second position to their said first position in a direction towards said distal end of said tubular catheter body, and in turn causing said wire mesh tip to return to its said contracted configuration.

2. The catheter according to claim 1 wherein said at least one expanded position of said wire mesh tip is a position selected from the group consisting of a fully expanded position, and a plurality of intermediate positions of partial expansion between said contracted position and said fully expanded position, such that in each of said intermediate positions, the diameter of said wire mesh tip is greater than its diameter in the said contracted position, less than maximum diameter in its said fully expanded position, and not greater than its maximum diameter of thirty times the outer diameter of said tubular catheter body, and the length of said wire mesh tip extending parallel to the axial direction of said catheter body is shorter than its length in the said contracted position, and greater than its length in its said fully expanded position; and

wherein said wire mesh tip is alternatively configurable from its said contracted position through selected intermediate positions to its fully expanded position; from its fully expanded position through selected intermediate positions to its contracted

position; from a first selected intermediate position to another selected intermediate position which is alternatively more expanded or more contracted than said first intermediate position, or from an intermediate position to said contracted or said fully expanded position;

the position and state of configuration of said wire mesh tip with respect to its expansion or contraction being proportional to said pulling force being exerted on said main control element through said remote control means.

3. The catheter according to claim 1 wherein said wire mesh tip is comprised of a plurality of rectangular wire mesh panels, with each panel having a proximal end, a distal end and two sides, said sides being longer than said ends, further with each panel terminating in a forward section having an outwardly facing curvilinear edge, each panel being longitudinally attached to an adjoining panel on both sides to form a substantially cylindrical configuration, and, alternatively, all or selected ones of said panels having one of said plurality of branch control wires attached thereto, at their said forward section.

4. The catheter according to claim 3 wherein said wire mesh tip is expandable through a plurality of intermediate positions between its said first, fully contracted position and its second, fully expanded position, where in each of said intermediate positions the diameter of said wire mesh tip is greater than its diameter in its said first contracted position and not greater than thirty times the outer diameter of said outer wall of said tubular catheter body, and the length of said wire mesh tip extending parallel to the axial direction of said tubular catheter body is shorter than its length in said first contracted position; and the diameter of said wire mesh tip is less than its maximum diameter in its said second position and the length of said wire mesh tip extending parallel to the axial direction of said tubular catheter body is greater than its length in said second fully expanded position; and

wherein said wire mesh tip is alternatively re-configurable through other intermediate positions to one of its first, fully contracted position and its second, fully expanded position;

the position and state of configuration of said wire mesh tip with respect to its degree of expansion or contraction being proportional to said extent of said pulling force being exerted on said control element through said remote control means.

5. The catheter according to claim 1 wherein the wire mesh material of said wire mesh tip is fabricated in a braided, woven or knot pattern,

wherein the wire mesh of said wire mesh tip is fabricated from a metal or plastic that is inert to fluid present in the lumen of the vessel in which said catheter is \deployed, said material being selected from the group consisting of stainless steel, nitinol (nickel-titanium alloy), titanium, vitallium and polyethylene; and

wherein the wire mesh material of said wire mesh tip has a mesh size that is permeable to the flow of fluid present in the lumen of the vessel in which said catheter is deployed.

6. The catheter according to claim 1 further comprising a wire for transmitting radio frequency energy, said wire extending the length of said tubular catheter body from the proximal end thereof to the distal end thereof, said wire being positioned in an annular space formed between said inner diameter of said tubular catheter body and said control element, said wire being connected at a distal end thereof to said wire mesh tip; and

a source for generating radio frequency energy connected to said wire at a proximal end thereof, external to said proximal end of said tubular catheter body.

7. The catheter according to claim 2 further comprised by:

an ablation electrode attached to said plate and insulated from said wire mesh tip;

a wire for transmitting electrical energy to said electrode, said wire extending through said length of said wire mesh tip, and being insulated therefrom, and further extending through the length of said tubular catheter body from said proximal end thereof to said distal end thereof, in said annular space between said inner wall of said tubular catheter body and said control element, and being insulated from said wire for transmitting radio frequency energy to said wire mesh tip, which is also contained in said annular space; and

a source for generating electrical energy for said ablation electrode connected to said wire for transmitting electrical energy at said proximal end of said wire, external to said proximal end of said wire which is external to said proximal end of said tubular catheter body.

8. A method for removing a flow obstruction from the lumen of a vessel comprising the steps of:

(a) inserting into the lumen a catheter having a flexible tubular body and a flexible open substantially cylindrical wire mesh tip attached at a proximal end thereof to a distal end of said tubular catheter body, with said wire mesh tip being in an initial contracted position wherein said wire mesh tip is configured to have dimensions of a contracted diameter approximately equal to said inner diameter of said tubular catheter body and a contracted position length;

(b) advancing said catheter through said lumen so that said wire mesh tip is positioned at the situs of said flow obstruction;

(c) actuating remote control means external to said catheter and connected to said wire mesh tip by wire mesh tip control means, to cause said wire mesh tip to be reconfigured to an expanded position at the situs of said flow obstruction, such that said wire mesh tip has an expanded diameter greater than its contracted diameter and not greater than thirty times said outer diameter of said tubular catheter body and a length equal to an expanded length in the axial direction of said tubular catheter body that is shorter than said contracted length, the expansion of said diameter of said wire mesh tip at said situs of said flow obstruction producing a compression of flow obstructing material against the tubular wall of said lumen to widen said passageway for flow through said lumen;

(d) deactivating said remote control means to cause said wire mesh tip to be restored to its said first contracted position; and

(e) withdrawing said catheter from the lumen.

9. The method according to claim 8 further comprising the steps, performed between steps (c) and (d), of:

(c') utilizing radio frequency energy supplied from a source external to the catheter and transmitted through at least one transmitting wire to said wire mesh tip to which a distal end of said at least one transmitting wire is attached, to energize said wire mesh tip to cut or ablate the flow obstructing material with which said wire mesh tip is in contact while in its said expanded position; and

(c'') providing suction through said catheter to remove any debris formed during cutting or ablation.

10. The method according to claim 8 wherein said catheter remains in place in the lumen of a vessel, with said wire mesh tip in an expanded position, for a period of time of up to about 48 hours.

11. The method according to claim 8 wherein said catheter remains in place in the lumen of a vessel, with said wire mesh tip in an expanded position, for a period of time of up to about 48 hours, with radio frequency energy being supplied to said wire mesh tip of said catheter only for a shorter duration during said period of time as required to cut or ablate said flow obstructing material.

12. The catheter according to claim 1 further comprising a guidewire for facilitating placement of said catheter in the lumen of a vessel.

13. The catheter according to claim 1 in which at least a part of the outer surface and external elements thereof, which come into contact with blood in the lumen of a vessel, are coated with at least one of a non-thrombogenic material and an elastomeric material.

14. The method according to claim 8 further comprising steps, performed before step (a), of:

(a') inserting a guidewire into the lumen and advancing it through said lumen to the situs of said flow obstruction, such that at least a portion of said guidewire remains external to said lumen at the point of insertion;

(a'') placing a catheter as described in step (a) onto said guidewire; and

further that said method is such that the insertion in step (a) and the advancement in step (b) of said catheter is done along said guidewire.

15. The method according to claim 8, further comprising the step, performed before step (a), of priming the catheter described in step (a) with at least one of a radiopaque contrasting solution, a saline solution, and a non-thrombogenic material.

16. The catheter according to claim 1 wherein said plate has a substantially circular cross section.

17. The catheter according to claim 1 wherein said wire mesh tip is at least partially covered with an elastomeric material selected from the group consisting of thermoplastic elastomers and silicone.

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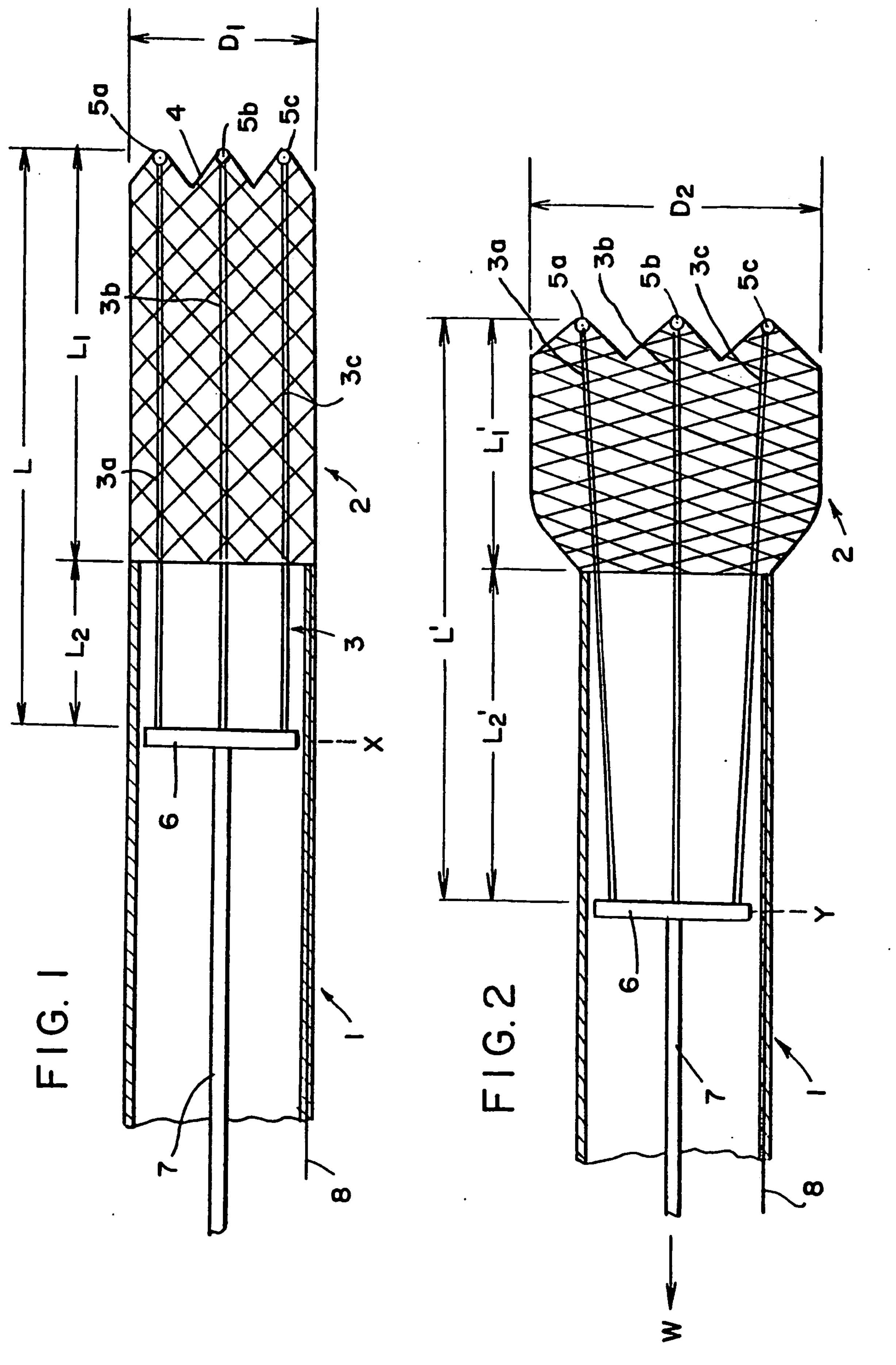
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FIG. 1

FIG. 2

FIG. 4

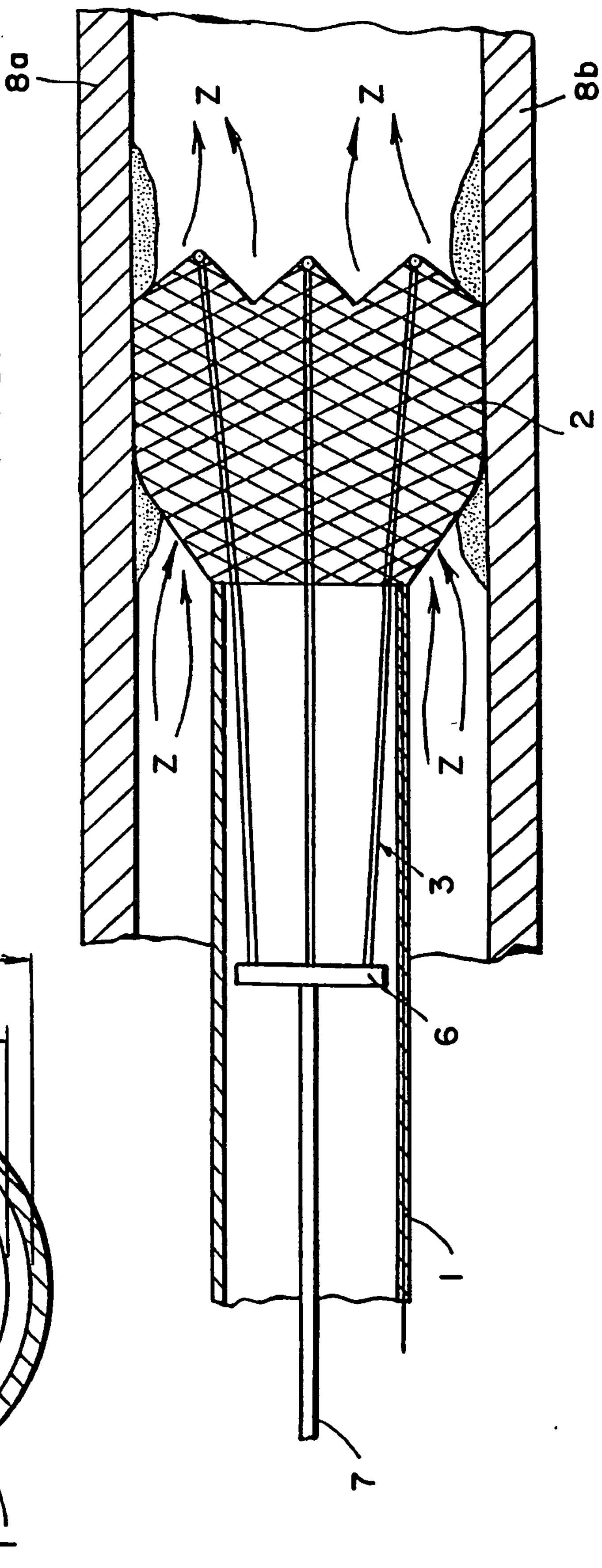
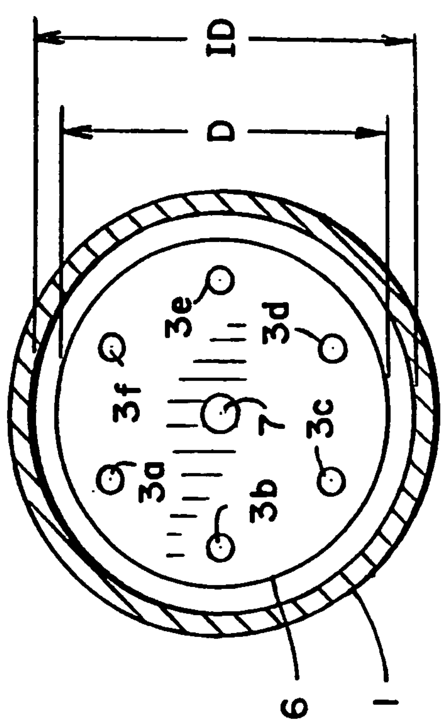


FIG. 3



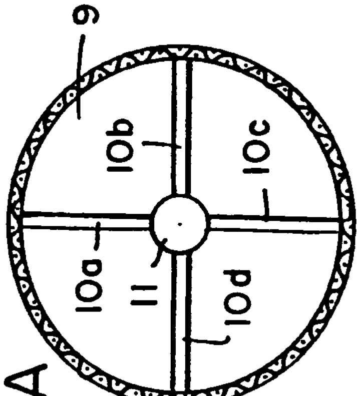


FIG. 5A

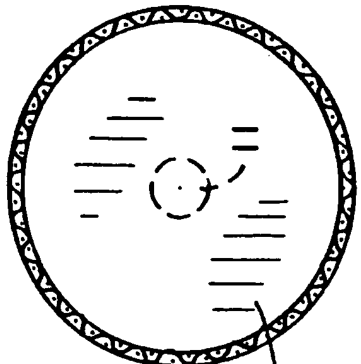


FIG. 5B

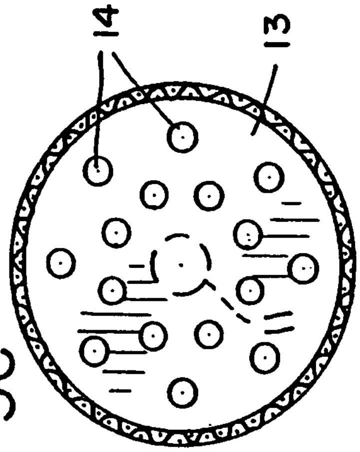


FIG. 5C

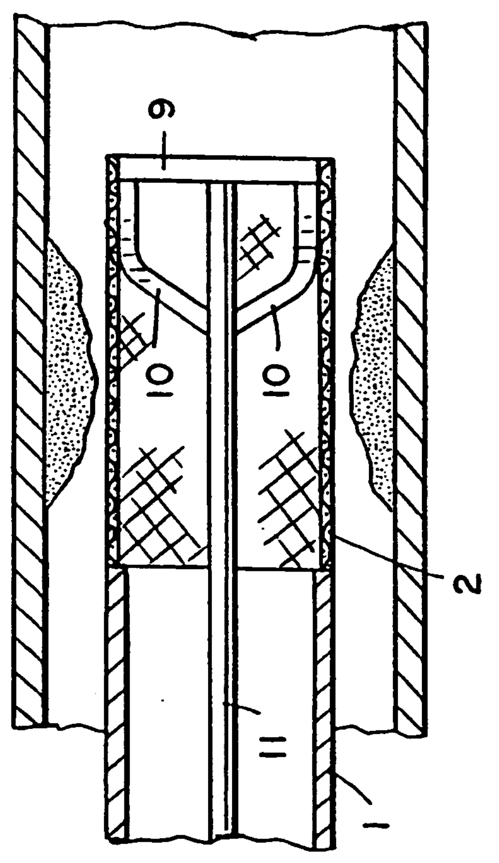


FIG. 6A

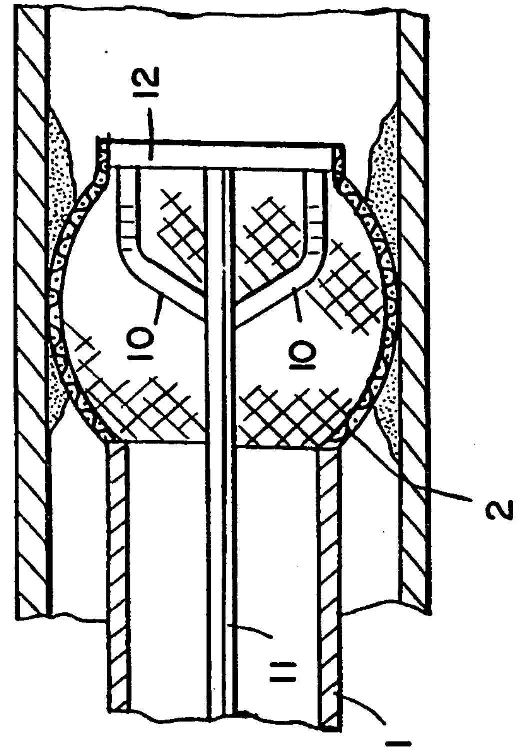


FIG. 6B

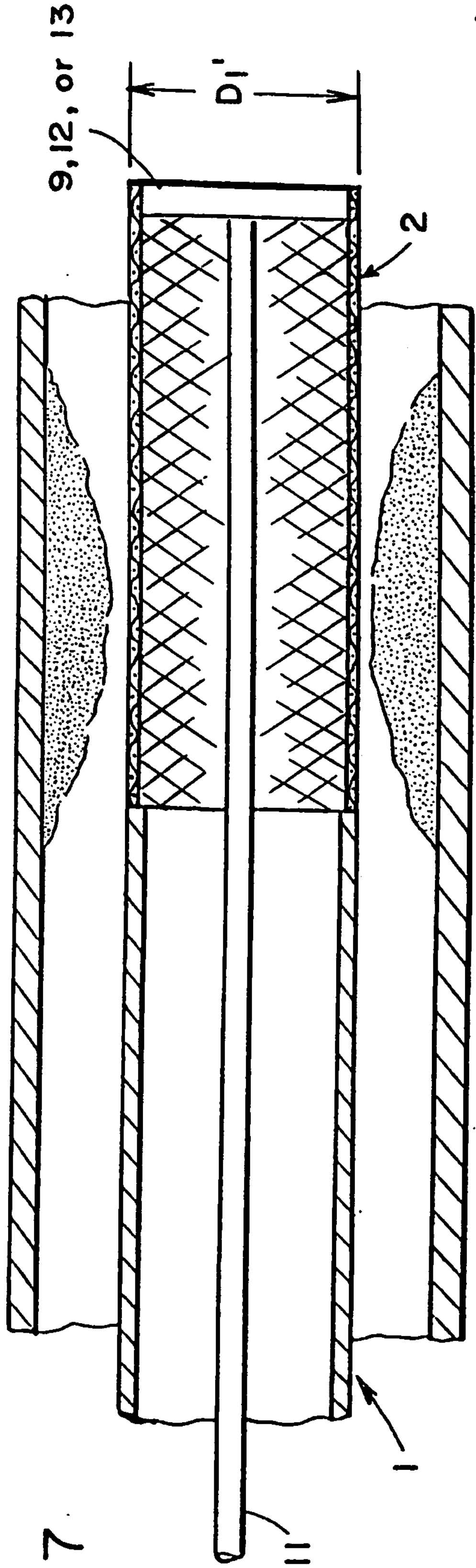


FIG. 7

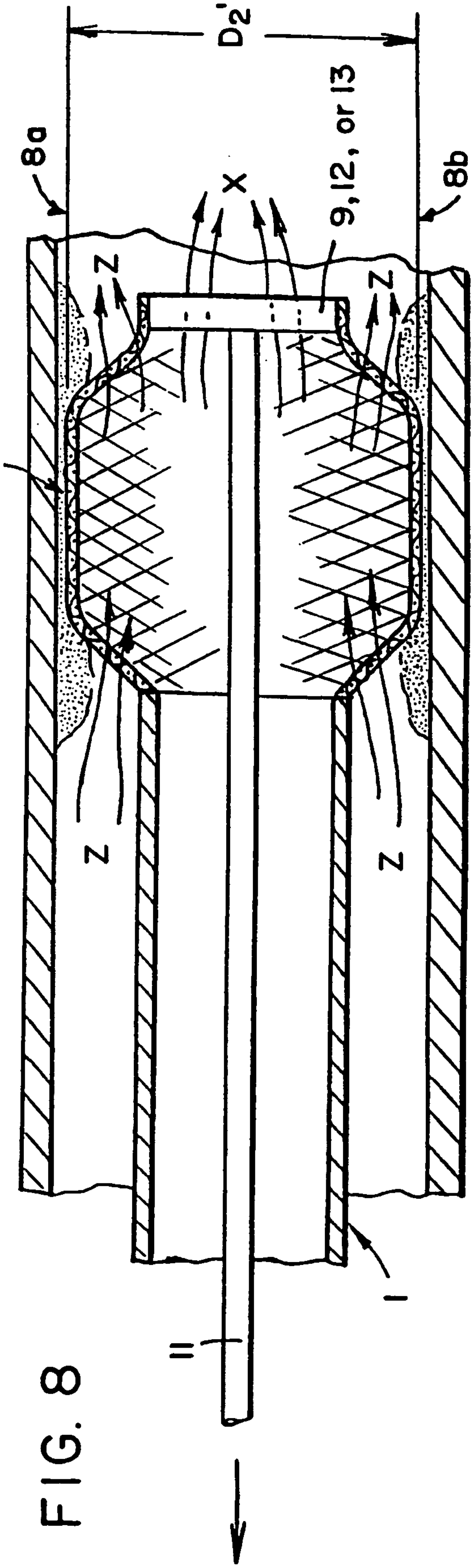


FIG. 8

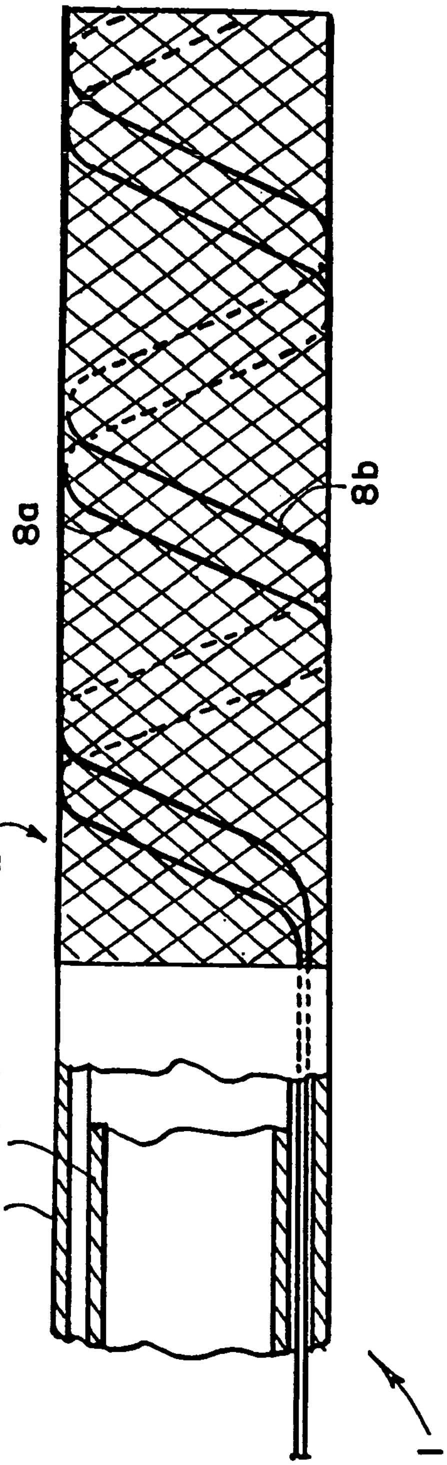


FIG. 9

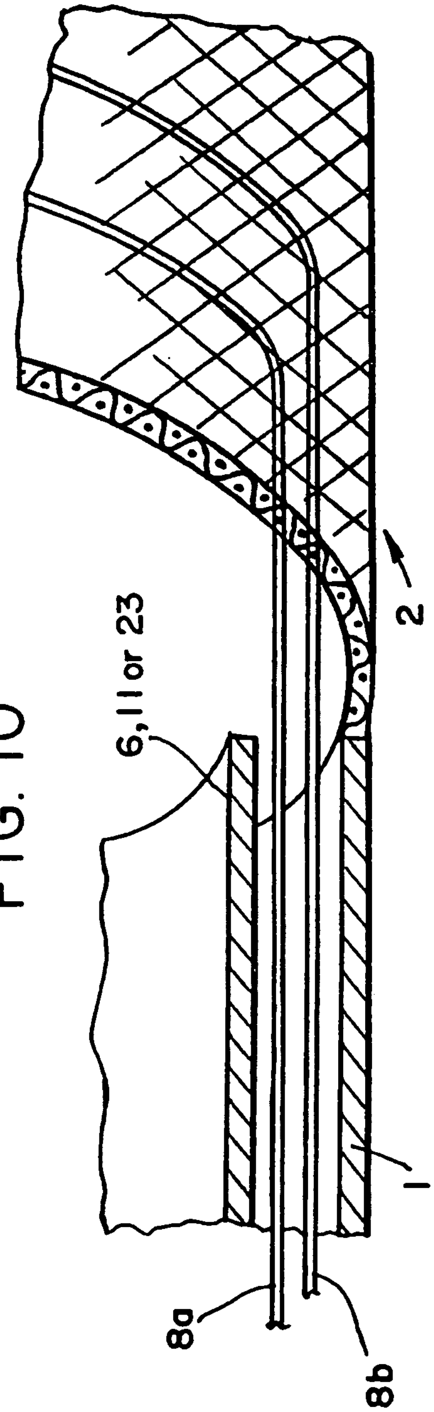


FIG. 10

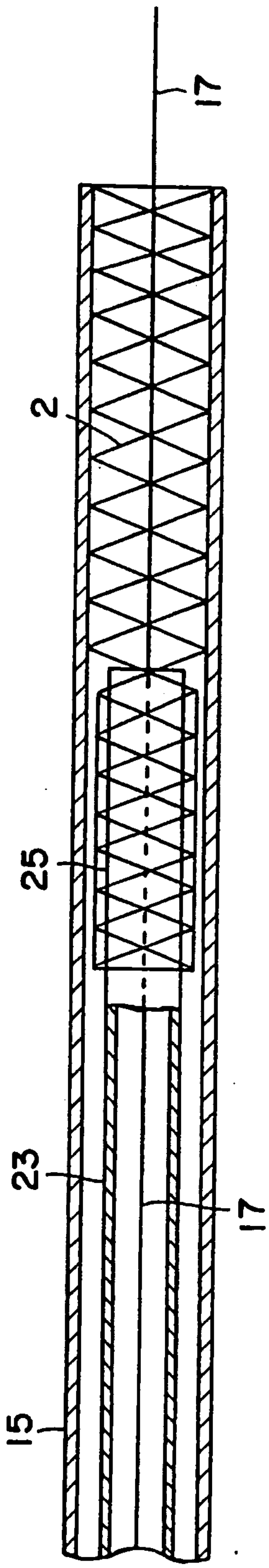


FIG. 11

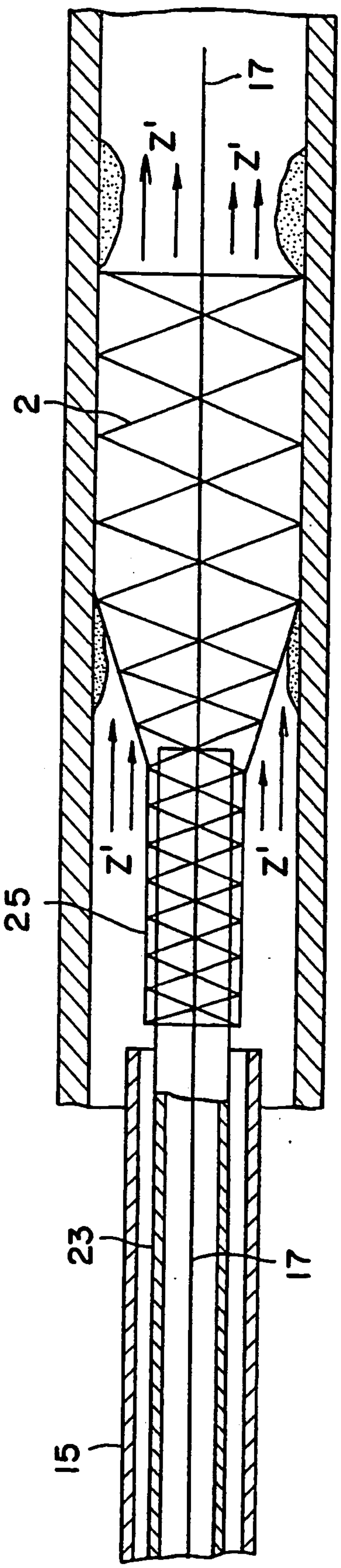


FIG. 12

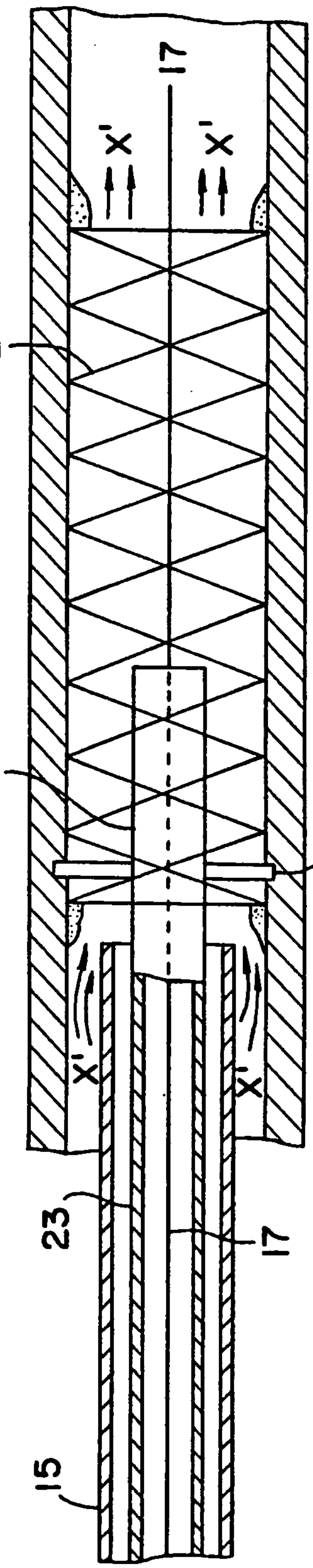


FIG. 13

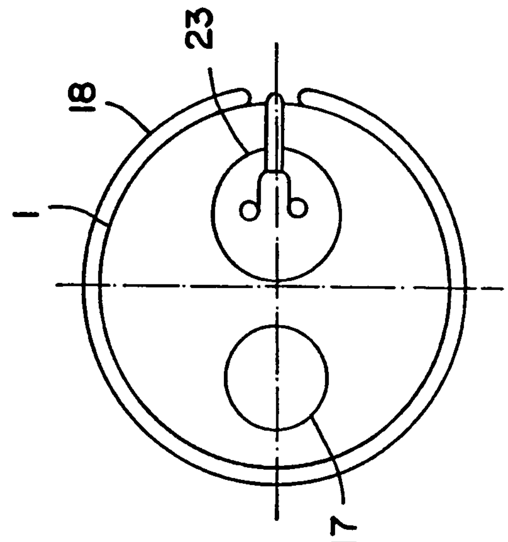


FIG. 14

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M29/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	EP,A,0 416 662 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 13 March 1991 see abstract; figures ---	1-2,5,8, 10-16
X	DE,U,9 109 006 (SCHMITZ-RODE) 10 October 1991 see claims; figures ---	1-2,5,8, 16-17
A	US,A,4 873 978 (GINSBURG) 17 October 1989 see column 3, line 39 - column 4, line 21; figures 2-3 ---	1-5
A	US,A,4 643 186 (ROSEN ET AL.) 17 February 1987 see claims; figures ---	6-7,9
	-/--	

° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

2

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
27 AUGUST 1993	07.09.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,5 053 048 (PINCHUCK) 1 October 1991 see abstract -----	13

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9304313
SA 74677

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0416662	13-03-91	US-A-	5034001	23-07-91
		CA-A-	2024823	09-03-91
		JP-A-	3176073	31-07-91
		US-A-	5180368	19-01-93
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US-A-4873978	17-10-89	None		
US-A-4643186	17-02-87	None		
US-A-5053048	01-10-91	None		

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82